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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte KRISTIN FEELEY and RAY LAREAU

Appeal 2009-005996
Application 10/786,021
Technology Center 3700

Decided: February 26, 2010

Before: JENNIFER D. BAHR, STEFAN STAICOVICI, and KEN B. BARRETT, *Administrative Patent Judges*.

BAHR, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Kristin Feeley et al. (Appellants) appeal under 35 U.S.C. § 134 (2002) from the Examiner's decision rejecting claims 1-5, 12, and 14-19. Claims 6, 9-11, 13, and 20 have been withdrawn from consideration. Claims 7 and 8 have been canceled. We have jurisdiction over this appeal under 35 U.S.C. § 6 (2002).

The Invention

Appellants' claimed invention is directed to an antimicrobial agent-bearing intervention device. Spec., para. 0007.

Claim 1, reproduced below, is illustrative of the claimed invention.

> 1. An antimicrobial agent delivery system comprising:
>
> an antimicrobial agent-bearing intervention device;
>
> a hub coupled to the intervention device; and
>
> a delivery tube having a perforated longitudinal partition with a hub opening;
>
> wherein the delivery system is configured so that longitudinal movement of the hub ejects the intervention device from the delivery tube.

The Rejections

The Examiner relies on the following references:

Chang	US 5,419,766	May 30, 1995
Suyeoka	US 3,595,230	Jul. 27, 1971
Utterberg	US 2003/0175323 A1	Sep. 18, 2003
Hall	US 2003/0212373 A1	Nov. 13, 2003
Hochman	US 6,726,658 B2	Apr. 27, 2004

Appellants seek review of the Examiner's rejections under 35 U.S.C. § 103(a) of claims 1-4, 12, 18, and 19 as unpatentable over Suyeoka, Utterberg, and Hall; claim 5 as unpatentable over Suyeoka, Utterberg, Hall, and Hochman; claims 14-16 as unpatentable over Suyeoka, Utterberg, Hall, and Chang; and claim 17 as unpatentable over Suyeoka, Utterberg, and Hall.[1]

SUMMARY OF DECISION

We AFFIRM.

ISSUE

The Examiner found that Suyeoka describes the intervention device of claim 1, with the exception that Suyeoka does not describe that the intervention device is an antimicrobial-bearing intervention device, or that the longitudinal partition is perforated. Ans. 3-4. However, the Examiner found that Utterberg describes an antimicrobial-bearing intervention device (rod) that serves to provide sterility during insertion (Ans. 3-4), and that Hall describes a perforated longitudinal sheath that guides the intervention device (Ans. 4, 8-9). Appellants argue that it would not have been obvious to incorporate the antimicrobial bearing intervention device of Utterberg into Suyeoka's device because Suyeoka already addresses sterility. App. Br. 4; Reply Br. 1. Appellants further argue that it would not have been obvious to

[1] In light of the dependence of claims 14-17 from claim 1, we interpret the Examiner's obtuse reference to "the modified Suyeoka" in the statement of the rejections of claims 14-17 (Ans. 5 and 6) as a reference to the combination of Suyeoka, Utterberg, and Hall set forth in the rejection of claim 1.

incorporate the perforations of Hall because Hall does not discuss the benefits of enhancing sterility, and such modification would prevent Suyeoka's device from operating in its intended manner because Suyeoka's shield is not intended to be peeled off in the manner disclosed in Hall. App. Br. 5; Reply Br. 2. Appellants argue that Hall discloses a flexible peel-away sheath, not a perforated longitudinal partition. App. Br. 5. Thus, according to Appellants, even if Suyeoka and Hall were combined, the result would not be a device having a perforated partition with an opening, as called for in claim 1. *Id.*

Appellants argue claims 1-4, 12, 18, and 19 as a group. Thus, claims 2-4, 12, 18, and 19 stand or fall with claim 1. 37 C.F.R. § 41.37(c)(1)(vii) (2009). Appellants separately argue claims 5, 14-16, and 17, but rely on the same arguments as presented for claim 1.

Therefore, the dispositive issues in the appeal are:

(1) Would it have been obvious to a person of ordinary skill in the art to modify Suyeoka's intervention device to include the antimicrobial-bearing agent of Utterberg, in order to improve the sterility of Suyeoka?

(2) Would it have been obvious to a person of ordinary skill in the art to modify the slot of Suyeoka's intervention device such that the slot is perforated, as described in Hall, in order to enhance the sterility of the device by allowing controlled removal of the sheath (Ans. 4)?

FACTS PERTINENT TO THE ISSUES

(FINDINGS-OF-FACT (FF))

FF1 Suyeoka describes a shield (tube) 2 placed around a catheter 6 that allows the catheter to be manipulated and handled during venipuncture without contamination. Col. 3, ll. 57-60, fig. 1. To aid in insertion, a fin 8 is affixed on a hub 10 at the rear of the catheter 6, with the fin 8 being guided through the shield 2 by a slot 52 that controls movement of the catheter through the shield, and eventually releases the catheter from the shield. Col. 3, ll. 30-31, 43-46, 57-62, figs. 2, 8. While the shield enables the needle and catheter to be manipulated without contamination, the shield 2 must be removed after venipuncture. Col. 3, ll. 57-62.

FF2 Utterberg describes an antibacterial fluid or gel applied to a needle or catheter. Para. 0017. This gel prevents the passage of microbes into the body at the puncture site, such as from bacteria on the skin or surrounding air dragged into the needle tract during puncture. Paras. 0009-12.

FF3 Hall describes both longitudinal and non-longitudinal weakened areas in the form slits or perforations to permit the sheath to be peeled away and removed from the catheter. Paras. 5, 51, 56, 57, and figs. 3a and 3b, noting both helical, non-longitudinal and straight, longitudinal perforation patterns.

PRINCIPLES OF LAW

Rejections on obviousness grounds must be supported by "some articulated reasoning with some rational underpinning" to combine the

known elements in the manner required in the claim at issue. *KSR Int'l. Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). However, "the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *Id.*

"[I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill." *Id.* at 417.

ANALYSIS

Issue (1) - Antimicrobial-Agent-Bearing Device

Appellants' argument that it would not have been obvious to incorporate the antimicrobial-agent-bearing intervention device of Utterberg into Suyeoka's intervention device because Suyeoka already addresses the issue of sterility is not persuasive. Suyeoka's device provides sterility by encapsulating the intervention device within a sheath. FF1. Utterberg's device provides sterility by coating the intervention device with antimicrobial agents. FF2. This prevents the microbes on the skin at the puncture site from being pushed into the vein. *Id.* Therefore, as explained by the Examiner (Ans. 7), Utterberg's device provides additional sterility to Suyeoka's device by addressing a different source of contamination. *See KSR*, 550 U.S. at 417 ("if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill."). Clearly, sterility is

a highly motivating factor in a healthcare environment. Thus, we do not find error in the Examiner's proposed combination of Suyeoka's intervention device with Utterberg's antimicrobial-agent-bearing device.

Issue (2) - Perforated, Longitudinal Delivery Tube

Appellants first argue that Suyeoka and Hall are "directed to such different devices." Appeal Br. 5. Appellants do not, however, cogently explain why the differences between Suyeoka's shield and the sheath of Hall are of such a nature that one of ordinary skill in the art would not have considered combining their features. As shown in our findings above, Suyeoka and Hall are both directed to a guiding shield or sheath for a catheter. FF1 and FF3. Furthermore, both Suyeoka's shield and Hall's sheath are intended to be removed from the catheter. FF1 and FF3. Hall teaches the use of a weakened area, in the form of perforations, for facilitating such removal. FF3. Thus, incorporation of the perforated weakened area as a means to facilitate the removal of Suyeoka's sheath after venipuncture appears to be the mere application of a known technique to a piece of prior art ready for the improvement. *See KSR*, 550 U.S. at 417.

Appellants next argue that Hall describes a flexible, peel-away sheath with a perforation in a non-longitudinal pattern. Appeal Br. 5. Appellants add that the flexibility of Hall's sheath would not allow Suyeoka to operate in its intended manner. Reply Br. 2. However, Appellants' arguments do not correspond to the combination proposed by the Examiner. The Examiner proposes to modify the *slot* in Suyeoka's tube to be perforated as described in Hall, not to swap out Suyeoka's tube for Hall's sheath. Ans. 4, 8-9. Thus, the Examiner is not proposing to modify Suyeoka's tube to be

"peel[ed]-away," perforated in a non-longitudinal pattern, or prohibitively flexible. Ans. 4, 8-9; *see In re Merck & Co. Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986) (nonobviousness cannot be established by attacking the references individually when the rejection is predicated upon a combination of prior art disclosures); *In re Keller*, 642 F.2d 413, 425 (CCPA 1981) (all of the features of the secondary reference need not be bodily incorporated into the primary reference). As the Examiner explains, the modification would provide Suyeoka's device with enhanced sterility by allowing controlled removal of the sheath. *Id.*

Further, Suyeoka's slot 52 is longitudinal, and Hall describes sheaths with perforated weakened areas in a longitudinal pattern. Suyeoka, fig. 2; FF3. Thus, Suyeoka's device would operate exactly as described in Suyeoka, but with the modification that the slot is initially sealed but perforated to allow the handle (fin) to pass through and the sheath to be removed, as taught in Hall. *See KSR*, 550 U.S. at 417 ("if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.").

To the extent that Hall doesn't explicitly state that the purpose of the sheath is to provide sterility, we note that disclosures need not explain common knowledge in the art. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379-80 (Fed. Cir. 1986) (information which is well known in the art need not be described in detail in the specification); *In re Sovish*, 769 F.2d 738, 743 (Fed. Cir. 1985) (one of ordinary skill in the art is presumed to have skills apart from what the prior art references expressly

disclose). Further, as noted above, the analysis supporting a conclusion of obviousness "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR*, 550 U.S. at 418. Clearly, the purpose of a catheter sheath such as Hall's is to provide sterility, as discussed in Suyeoka.

CONCLUSIONS

(1) The record before us indicates that it would have been obvious to modify Suyeoka's intervention device to include the antimicrobial-bearing agent of Utterberg, which serves to improve the sterility of Suyeoka.

(2) The record before us indicates that it would have been obvious to modify the slot of Suyeoka's intervention device such that the slot is perforated, as described in Hall, which serves to enhance the sterility of Suyeoka's shield while also permitting its controlled removal.

Therefore, we sustain the Examiner's rejection of claims 1-4, 12, 18, and 19. Likewise, we sustain the Examiner's rejections of claims 5, 14-16, and 17.

DECISION

The Examiner's decision is affirmed as to claims 1-5, 12, and 14-19.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv) (2007).

AFFIRMED

hh

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